REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 19-33 remain pending in the application subsequent to entry of this Amendment.

The examiner's attention is invited to the concurrently filed Information Disclosure Statement which includes journal articles cited by the International Search Authority and documents cited in the corresponding European patent application and documents identified and discussed in the subject application itself.

As an initial matter, while claim 33 is listed among the rejected claims, there is no specific rejection directed to claim 33. Accordingly, it is applicants' understanding that claim 33 is allowable.

Response is now provided to the various parts of the Official Action in the order listed in the Action itself.

1-2) The Examiner initially rejects claims 31 and 32 on the basis that the specification does not allow the skilled worker to carry out the invention over the whole scope of the claims. The Examiner analyses whether the undue experimentation would be necessary in order to carry out the invention and in particular, addresses whether all types of allergic rhinitis could be "prevented or treated" by a single composition. The Examiner additionally points out that "there is no single pharmaceutical preparation/treatment available which treats or reduces all symptoms of allergic rhinitis". The Examiner's comments do not accurately address the subject matter of claims 31 and 32.

When one carefully reads claims 31 and 32 the essential point to appreciate about the present invention is that it does not claim to *treat* allergic rhinitis. The Examiner is quite correct in that the inflammation caused by this condition is difficult to treat and symptomatic relief typically addresses only one or two specific symptoms. What is claimed by the present application is a method to *prevent* allergic rhinitis. This is a completely different situation to treatment, since there are no symptoms to treat at this stage, and thus no issue as to whether all symptoms are treated.

If the condition is prevented then all associated symptoms will necessarily be prevented also.

It is extremely easy to prevent allergic rhinitis; one need simply keep the patient in a

sterile bubble isolated from aerial contaminants. This is a mechanical isolation and relies on no pharmaceutical interactions or *in vitro* testing. It is highly predictable and effective against all types of allergic rhinitis but is rather inconvenient for the patient. Although much less onerous on the subject, essentially the same approach is adopted by the present inventors; the compositions of the invention generate a barrier across which particulate contaminants are unable to pass. It makes no difference to the method of the invention which contaminant is responsible or which inflammatory pathway is involved. If the particle does not reach the mucosal surface it cannot cause inflammation.

As discussed in the application text at page 6, lines 13 to 29, the compositions of the present invention are highly effective because they serve both to quench any surface charge on an airborne particle and trap both hydrophobic and hydrophilic particles due to the dual nature of the emulsion. The compositions are thus usable in the prevention of *any* form of allergic rhinitis caused by airborne particles. Exactly the same method as demonstrated for pollen grains can be used for other particles irrespective of their origin, and indeed without knowing which particles are causing the issue. One need only coat the surface to be protected and the particles will be trapped, preventing them from reaching the site of potential inflammation.

In view of the above, it is clear that the inventors' contribution is a composition effective against all types of airborne causes of allergic rhinitis which can be implemented with no need for experimentation on the part of the skilled worker. The working examples provided give a method which can be applied directly in all cases and have thus applicants made a contribution commensurate with the claimed scope of protection.

In the final part of this section the Examiner states "since the efficacy of microemulsion compositions in *preventing or treating* allergic rhinitis mentioned above cannot be predicted ... but must be determined for the case to case experimental study ... one of ordinary skill in the art would be burdened with undue "painstaking experimentation study". Again, the present claims do not relate to *treatment.* What is both claimed and provided in the present case is a method of prevention, and prevention can be provided by a universal remedy; prevent the allergen reaching the site of action.

3 A typographical error in claim 28 is objected to. This is corrected in the revised claim set.

4,6 The Examiner rejects claims 19-30 on the basis that these claims are considered obvious over Baker in view of Wright.

An important issue to note in the context of non-obviousness is the definition of the compositions as presently claimed. In particular the solvent content stated is 10 to 55% by weight of the composition and corresponds to the proportion of solvent illustrated in the Examples of the application as filed. This relatively low proportion of solvent will result in *reversed phase* microemulsions (being emulsions of water suspended in oil) rather than *normal phase* emulsions (in which oil is suspended in water).

The present inventors have now established that the low proportion of solvent and the specific components and proportions recited in the claim, result in water-in-oil emulsions which are film-forming, non-breaking compositions having the properties discussed above and on page 6 of the application. In contrast, normal phase oil-in-water emulsions "break" upon contact with a body surface generating an oily film which cannot quench the charge on airborne particles.

By contrast to the present claims, the compositions of Baker are normal phase (oil in water) emulsions (see abstract). Such emulsions have quite different properties to those presently claimed, and in particular do not show the necessary film-forming and non-breaking behavior which allows the claimed compositions to trap and retain allergenic particles. The disclosure of Barker supports this view, since Barker does not claim to prevent contact between the treated surface and the contaminant. The function of the emulsions of Barker is to inactivate a pathogenic substance such as a spore or bacterium (see abstract and column 8 lines 35 to 43). Inactivation cannot serve to prevent allergic rhinitis because this is not caused by a "live" pathogen. Allergic rhinitis is caused by the subject's own body reacting inappropriately to the allergen and thus no "inactivation" is possible.

There is no teaching in Baker which would cause the skilled person to make the reversed phase emulsions of the present application, and Baker does not address the issue of allergic rhinitis, so there can be no motivation to look for compositions which quench airborne particles in this way.

As the Examiner notes, Barker does not disclose the components and proportions claimed and Wright discloses only oil-in-water emulsions which again cannot lead to reversed phase compositions. One might modify the compositions of Barker in view of Wright, but without any

teaching in either document relating to the entrapment of air-bourn particles, the skilled worker would not arrive at the present compositions because he would not know that he had generated an advantageous microemulsions. A huge number of compositions could potentially be generated from the combination of Baker with Wright. Without any teaching of any advantage or property to look for, there is essentially no chance that a skilled worker would happen to stumble upon the compositions of the present invention, and if he did so, he would not know their value. It is only in the knowledge of the present invention that a skilled worker would look for the compositions claimed, and without looking for them he could never hope to find them.

This argument applies equally to the device claims, since these incorporate the microemulsions and compositions of the invention.

1 In the final substantive section of the Office Action, the Examiner rejects claims 31 and 32 as obvious over the combination of Baker, Wright and Chilton. The Examiner correctly notes that Baker and Wright are devoid of any teaching or disclosure relating to rhinitis and cites Chilton for this shortfall.

The aim of Chilton is the *treatment* of inflammatory diseases, especially the symptoms thereof (see abstract). In particular, the Examiner indicates paragraph [0020], which relates to milk-based drinks for treatment of lipid-related disorders, certain inflammatory diseases, and a "laundry list" of several dozen other disorders from organ failure to repetitive strain injury. These many disparate conditions include allergic rhinitis.

The compositions of Chilton are milk based drinks for oral consumption and thus include constituents such as flavoring and sweetening agents (see paragraph [0028], as indicated by the Examiner). It is notable in contrast that the methods of the present invention involve *prevention* of allergic rhinitis by application to a body surface or external mucosal membrane of a subject.

Since Chilton is silent with regard to the entrapment of airborne particles, it cannot cause the skilled worker to look for compositions which will effectively capture such particles. Furthermore, it is silent on the *prevention* of allergic rhinitis, and thus cannot cause the skilled worker to modify the teaching of the other citations in this respect. The Examiner indicates:

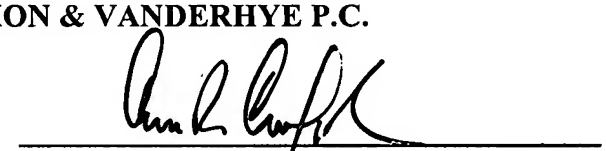
> "it would have been obvious to one of ordinary skill in the art to modify the emulsion composition disclosed in Baker and Wright and using the composition for the *treatment of symptoms/preventing* allergic rhinitis, *Subjects consuming the oral emulsion* show enhanced bioavailability ..."

The present invention, however, does not relate to treatment and most definitely does not relate to oral consumption. Claims 31 and 32 explicitly recite *prevention,* which in fact is not addressed by Chilton and is a completely different issue to treatment of symptoms. Furthermore, these claims quite clearly recite topical application methods rather than the oral application which even the Examiner indicates is taught by Chilton. In view of this, it is clear that none of the present claims are rendered obvious by any combination of the cited prior art.

For the above reasons it is respectfully submitted that claims 19-32 are allowable together with allowable (apparently) claim 33. Should the examiner require further information, please contact the undersigned.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

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